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CONFIRMATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE 12/23/2003 CRYA,025/CIP 9376 10/743,956 Yin Chen 02/08/2006 EXAMINER 7590 Wisner & Associates GROSS, CHRISTOPHER M Suite 400 ART UNIT PAPER NUMBER 1177 West Loop South Houston, TX 77027-9012 1639

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>	Application No.	Applicant(s)	
Office Action Summary	10/743,956	CHEN ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	
The MAILING DATE of this communication app	<u>. </u>		
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on <u>28 June 2004</u> .			
2a) ☐ This action is FINAL . 2b) ☑ This	n) This action is FINAL . 2b) ⊠ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) Claim(s) 1-15 is/are pending in the application.			
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6) Claim(s) is/are rejected.			
7) Claim(s) is/are objected to. 8) Claim(s) <u>1-15</u> are subject to restriction and/or election requirement.			
o) Claim(s) 1-10 are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
Attachment(s)			
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 	4) Interview Summary Paper No(s)/Mail Da		
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal P	atent Application (PTO-152)	
Paper No(s)/Mail Date 6) Other:			

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DETAILED ACTION

1. Claims 1-15 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claim 1, drawn to a random library product comprising oligodeoxynucleotides, classified in class 435, subclass DIG 37.
- II. Claims 2 and 3, drawn to a process of identifying a particular species of oligonucleotide, classified in class 435, subclass 6.
- III. Claim 4-11, drawn to vectors and expression host products, classified in class 435, subclass 320.1.
- IV. Claims 12-15, a discrete single-stranded DNA enzyme, classified in class536, subclass 23.1.
- 2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of group I as claimed can be used in a materially different process such as for the generation of a random protein library thus not necessarily used exclusively for the process of group II. Therefore, inventions I and II are related as product and process of use. Prior art searches of the random sequence oligonucleotides of group I and a method of using said random oligonucleotides with the process of group II are not coextensive. Search

of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular method steps concerning invention II, such as colony screening, not required for the search of invention I. These searches would then require subsequent in-depth analysis of all relevant prior art literature and sequence references, placing a serious and undue burden on the Office in terms of both search and examination if I and II are put together.

3. Inventions II versus III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the vector products of group III could be used to simply prepare antibiotic resistant bacteria, thus not exclusively for the process of group II. Therefore, inventions II and III are related as product and process of use. In the instant case, prior art searches of the DNA vectors of group III and a method of using said vectors under the process of group II are not coextensive. A search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular elements of invention III, such as the genetic constituents of the plasmid pssXG not required for more methodological search related to invention II. These searches would then require subsequent in-depth analysis of all relevant prior art literature and sequence references, placing a serious

and undue burden on the Office in terms of both search and examination if II and III are put together.

- 4. Inventions I and III are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been shown as capable of use together and inventions I and III have different effects. The plasmid pssXG of Invention III can be used to transform bacteria whereas the oligonucleotide library of invention I can not be used for transformation. Prior art searches of each product are not coextensive. A search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular elements of invention III, such as the genetic constituents of the plasmid pssXG not required for more library centered search of invention I. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination if I and III are put together.
- 5. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of group IV as claimed can be used in a materially different process such as measuring

DNA-enzyme kinetics. Therefore, inventions I and IV are related as product and process of use. Search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular method steps of invention IV such as catalysis measurements not required for the search of invention I. These searches would then require subsequent in-depth analysis of all relevant prior art literature and sequence references, placing a serious and undue burden on the Office in terms of both search and examination if I and IV are put together.

6. Inventions III and IV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been shown as capable of use together and inventions IV and III have different effects. The plasmid pssXG of Invention III can be used to transform bacteria whereas the DNA enzyme of invention IV can not be used for transformation. Prior art searches of each product are not coextensive. A search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular method steps, of invention IV, such as catalysis measurements not required for the gene centered search of invention III. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination if III and IV are put together.

7. Inventions II and IV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been shown as capable of use together and inventions IV and II have different effects. In the instant case group IV as claimed can be used for measuring DNA-enzyme kinetics, which is not possible with the screening methodology that is invention II. Prior art searches of the DNA enzymes of group IV and a method of screening that is group II are not coextensive. A search of each of these inventions would require different key word and sequence searches in different patent, non-patent literature and sequence databases and require, at least, specific searches for particular elements of invention IV, such as the partially defined nucleotide sequence of clam 13, not required for more methodological search related to invention II. These searches would then require subsequent in-depth analysis of all relevant prior art literature and sequence references, placing a serious and undue burden on the Office in terms of both search and examination if II and IV are put together.

Because each of these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai. In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Mark Wisner on January 18, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher M Gross Examiner

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Mark Shibuya
Examiner

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